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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,757	09/21/1999	GARY S. HAHN	246/221	3773

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THE GRIFFITH LAW FIRM, A P.C.
991 C Lomas Santa Fe Drive
Suite 450
Solana Beach, CA 92075

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/400,757

Applicant(s)

HAHN ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,10-25,55,57,58,61-69,77-80,84,85 and 98-119 is/are pending in the application.
- 4a) Of the above claim(s) 19,20,62-69,77-80,84,85 and 98-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,10-18,21-25,55,57,58,61 and 115-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted May 17, 2005 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7 recites "comprising an amount of calcium cation capable of *inhibiting mean cumulative skin irritation* attributed to said irritant ingredient in a susceptible human population *by at least about 20%* up topical application of said composition." However, the application fails to provide a proper written description for quantitative determination of mean cumulative irritation as required in this claim.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claim 7 recites “comprising an amount of calcium cation capable of *inhibiting mean cumulative skin irritation* attributed to said irritant ingredient in a susceptible human population *by at least about 20%* up topical application of said composition.” However, the specification or the claims fails to provide a clear standard as to the degree of *inhibiting mean cumulative skin irritation*, and the mean to determine it. The claim is indefinite as to the degree of inhibiting and the amount of calcium cation required in the claimed composition.

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 4-5, 7, 10, 12, 22, 24, 116-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Daggy et al. (5,422,101).

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Daggy teaches a composition comprising 0.1 to 50% of one of the salts, including calcium chloride, calcium sulfate, calcium citrate malate, and 0.1 to 10% of acid, including ascorbic acid, malic acid, tartaric acid. See, particularly, col. 6, lines 27-39, and the claims. As to the limitation "topical composition," in claim 1, and cosmetic composition in claim 10, note it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

Claim Rejections 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4-5, 7, 10, 12, 22, 24, 116-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daggy et al. (5,422,101).

Daggy teaches a composition comprising 0.1 to 50% of one of the salts, including calcium chloride, calcium sulfate, calcium citrate malate, and 0.1 to 10% of acid, including ascorbic acid, malic acid, tartaric acid. See, particularly, col. 6, lines 27-39, and the claims. As to the limitation "topical composition," in claim 1,, and cosmetic composition in claim 10, note it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

5. Daddy et al. do not teaches expressly the particular amounts of metal salts herein.

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However, since the amounts herein employed is falls within the range disclosed by Ito, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition with the amounts of metal salts being within the range taught by Daggy et al.

6. Claims 1, 4-5, 7, 10-18, 21-25, 55, 57, 58, 61, and 115-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mishima (5,262,153, IDS) in view of Ito (U.S. Patent 5,709,849), Giddey et al. (U.S. Patent 5,053,219), Cook et al. (U.S. Patent 2,719,811) and Henderson (U.S. Patent 5,296,476).

7. Mishima et al. teaches a cosmetic composition comprising mixture of lactic acid and lactate of alkali metal, or alkaline metal with a pH in the range of 2.5-9, wherein the amount of lactic acid and lactate is at least 5% by weight. See, particularly the claims. Calcium lactate is exemplified. See the examples.

8. Mishima et al does not teach expressly the employment of calcium, or the particular amount of the calcium, organic acid, or the particular pH, or the counter anion, or the other known cosmetic ingredients herein.

9. However, Cook et al. teaches that calcium metal with hydroxyl acids are known to be beneficial for skin. See, particularly, column 2, lines 30-40, lines 63-72, and claims 4-5.

Henderson teaches that calcium citrate is particularly useful with salicylic acid in topical application. See, particularly the claims. Ito also teaches the usefulness of organic salts of calcium in cosmetic products. See, particularly, the abstract, and the claims. The organic salt may be produced in situ, i.e., employing an inorganic calcium salt (e.g., calcium chloride) and an

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organic acid in the cosmetic composition, see, the entire document, particularly, the examples and the claims. Giddey et al. teaches cosmetic composition having an organic acid (0.5-4% by weight) and calcium cation (0.1-1%, by weight), see the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ calcium lactate in the cosmetic composition with lactic acid, in the amount herein define, and with the pH herein.

A person of ordinary skill in the art would have been motivated to employ calcium lactate in the cosmetic composition with lactic acid, in the amount herein define, and with the pH herein because calcium with hydroxyl acid are particularly known to be beneficial for skin. Further, A person of ordinary skill in the art would have been motivated to employ calcium as the divalent metal in cosmetic composition, wherein a hydroxyl acid is required because calcium with organic acid are known to provide benefit to skin, and calcium cation is particularly known to be useful in some cosmetic product. The employment of other well-known cosmetic or topical ingredients, such as sulfate, nitrate, second anti-irritant agent, steroid, etc, in the topical composition is considered obvious and is with the skill of artisan. Further, optimization within the range disclosed by prior art is obvious and is considered within the skill of artisan.

1. Regarding the functional limitation of the claimed composition, i.e., note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant

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invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various functional limitations. The ultimate utility for the claimed combination of organic acid and calcium is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Response to the Arguments

Applicants' amendments and remarks submitted May 17, 2005 have been fully considered, but are not persuasive.

6. As to the rejections under 35 U.S.C. 112, note the rejections is not a new matter rejections. As stated above, Claim 7 recites "comprising an amount of calcium cation capable of *inhibiting mean cumulative skin irritation* attributed to said irritant ingredient in a susceptible human population *by at least about 20%* up topical application of said composition." However, the application fails to provide a proper written description for quantitative determination of mean cumulative irritation as required in this claim, thereby fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that Daggy et al. do not anticipated the claimed invention. Specifically, applicants point to example 2 in Dadggy et al. wherein the amount of calcium cation is less than what is required herein. The arguments are not persuasive. As stated in column 8, lines 5-12 in Daggy et al., those examples "are given solely for the purpose of illustration and are not to construed as limitations the present inventions as many variations thereof are possible without

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departing from the spirit and scope. Further Daggy et al. provide sufficient specificity for the claimed range. Specifically, Daggy et al. teach higher concentration of calcium cation would lower the viscosity of the suspension. See column 8, line 56 to column 9, line 8. Daggy et al. provide sufficient specificity for a composition comprising higher concentration of calcium chloride. Therefore, the claimed invention is either anticipated by or obvious over Daggy et al. As to the irritant ingredient, note Daggy teach the composition comprising up to 25% of organic acid. Further, it is noted that Daggy et al. teach, or fairly suggest, a composition that meet the limitation herein claimed. Whether, the composition need to be further diluted before use is not relevant to the rejections herein.

7. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., aqueous solution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

2. In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge

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generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found both in the cited references and in the knowledge generally available to one of ordinary skill in the art. The claims are directed to a composition comprising a substantially amounts of organic acid and calcium compounds. Mishima et al. teaches a cosmetic composition comprising mixture of lactic acid and lactate of alkali metal, or alkaline metal with a pH in the range of 2.5-9, wherein the amount of lactic acid and lactate is at least 5% by weight. See, particularly the claims. Calcium lactate is exemplified. See the examples. Therefore, Mishima et al. teaches a broad scope that encompass (calcium, as metal ion), or overlap (organic acid, pH, anionic ions) with claimed invention. Cook et al. further teaches that calcium metal with hydroxyl acids are known to be beneficial for skin, and provide motivation to employ calcium as the metal ion in the composition Mishima et al. Henderson teaches that calcium citrate are particularly useful with salicylic acid in topical application, and provide further motivation to employ calcium in topical composition, wherein salicylic acid present. Ito also teaches the usefulness of organic acid salts of calcium in cosmetic products. See, particularly, the abstract, and the claims. The organic salt may be produced in situ, i.e., employing an inorganic calcium salt (e.g., calcium chloride) and an organic acid in the cosmetic composition. Giddey et al. teaches cosmetic composition having an organic acid (0.5-4% by weight) and calcium cation (0.1-1%, by weight). The teachings provided by Ito and Gaddy fairly suggest that it is beneficial to combine calcium with organic acids. Taking the cited references as a whole, the combination of organic acids with calcium in a topical or cosmetic composition would have been obvious.

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11. The references may not state expressly that the compositions taught or suggested therein are without irritating. However, one of ordinary skill in the art should understand that “without irritating” is an essential requirement for cosmetic or topical composition. Therefore, it would have been reasonable expected that the compositions taught or suggested by the references would be without irritating effect. Further more, “[a]s long as some motivation or suggestion to combine the references is provided by the prior art taken as whole, the law does not require that the references be combined for the reasons contemplated by inventor.” *In re Beattie* 974 F.2d at 1312 (Fed. Cir. 1992).

12. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUNWANG
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617